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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,120	10/17/2001	Sanford M. Simon	600-1-280N	9363

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EXAMINER
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WEHBE, ANNE MARIE SABRINA

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 11/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/982,120

Applicant(s)

SIMON ET AL.

Examiner

Anne Marie S. Wehbe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 September 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 and 22-55 is/are pending in the application.
- 4a) Of the above claim(s) 33-51 and 53 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-2, 4, 7-10, and 52 is/are allowed.
- 6) ☒ Claim(s) 3,5,6,11-19,22-32,54 and 55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Applicant's amendment and response received on 9/19/05 have been entered. Claims 20-21 are canceled. New claims 54-55 have been added. Claims 1-19 and 22-55 are pending in the instant application. This application contains claims 33-51 and 53 drawn to an invention nonelected with traverse in applicant's submission dated 10/10/03. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. Claims 1-19, 22-32, 52, and 54-55 are currently under examination. An action on the merits follows.

Those sections of Title 35, US code, not included in this action can be found in a previous office action.

### ***Claim Rejections - 35 USC § 112***

The previous rejections of claims 1-19, and 21-32 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of applicant's cancellation of claim 21 and the amendments to claims.

Applicant's amendments to the claims, however, have necessitated the following new grounds of rejection under 35 U.S.C. 112, second paragraph.

Claims 3, 5, 6, 11-19, 22-32, and 54-55 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites the mammal of claim 2, “wherein a polynucleotide encoding said at least two detectable proteins present at the C-terminus of the gene product of said fusion polynucleotide are located in exon G1”. Claim 1, upon which claim 3 ultimately depends has been amended to delete the language of a polynucleotide sequence encoding a detectable protein. Claim 1 as amended now refers to a fusion polynucleotide comprising a nucleic acid encoding at least two detectable proteins. As such, it is unclear whether the polynucleotide referred to in claim 3 is the same or different from the fusion polynucleotide. It is suggested that the applicant amend claims 3 to recite , “wherein said nucleic acid encoding said at least two detectable proteins...”.

Claim 5 depends on claim 4, which depends on claim 1. Claim 5 recites “wherein a polynucleotide encoding said at least two detectable proteins present at the C-terminus of the gene product .....”. Claim 1, upon which claim 3 ultimately depends has been amended to delete the language of a polynucleotide sequence encoding a detectable protein. Claim 1 as amended now refers to a fusion polynucleotide comprising a nucleic acid encoding at least two detectable proteins. As such, it is unclear whether the polynucleotide referred to in claim 3 is the same or different from the fusion polynucleotide. It is suggested that the applicant amend claims 5 to recite , “wherein said nucleic acid encoding said at least two detectable proteins...”.

Furthermore, claim 5 as amended is confusing in that it is unclear whether the flexible linker is actually encoded by the fusion polynucleotide.

Claim 6 recites the limitation "said immunoglobulin heavy chain gene" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 11 recites the limitation "the polypeptide" in claim 1. There is insufficient antecedent basis for this limitation in the claim. Further, since claim 1 refers to a fusion polynucleotide, it is unclear whether the linker sequences referred to are amino acid sequences or nucleic acid sequences. Claims 12-16, and 54 depends on claim 11 and are therefore included in this rejection.

Claim 17 is confusing in that as amended the claim recites a fusion polynucleotide comprising a nucleic acid encoding an immunoglobulin component and a nucleic acid encoding at least two detectable protein, "wherein a flexible linker peptide is located between the immunoglobulin and the at least two detectable proteins..". Since the claim refers to a polynucleotide, it is unclear whether the applicant intends that the polynucleotide actually include a linker peptide or whether the applicant means to claim that the fusion polynucleotide further comprises a nucleic acid sequence encoding a flexible linker peptide located between the nucleic acid encoding the immunoglobulin component and the nucleic acid encoding the at least two detectable proteins. Claims 18-19, 22-32, and 54 depend on claim 17 and thus are included in this rejection.

Claim 19 depends on claim 17. Claim 19 recites "wherein a polynucleotide encoding said at least two detectable proteins present at the C-terminus of the gene product ....." . Claim 17, upon which claim 19 depends has been amended to delete the language of a polynucleotide

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sequence encoding a detectable protein. Claim 17 as amended now refers to a fusion polynucleotide comprising a nucleic acid encoding at least two detectable proteins. As such, it is unclear whether the polynucleotide referred to in claim 19 is the same or different from the fusion polynucleotide. It is suggested that the applicant amend claims 19 to recite, "wherein said nucleic acid encoding said at least two detectable proteins...".

Claim 22 recites the limitation "said immunoglobulin heavy chain gene" in claim 17. There is insufficient antecedent basis for this limitation in the claim.

Claim 55 depends on claims 11 or 27 and recites, "wherein said detectable protein may be one of at least two detectable proteins or a plurality of detectable proteins, in tandem or not in tandem". The claim is confusing because the base claim upon which it depends, claims 1 or 17 respectively, refer to a fusion polynucleotide encoding at least two detectable proteins. Thus, the mammals or cells are already limited to at least two detectable proteins. It is therefore unclear how claim 55 is intended to further limit the parent claims. It is also unclear which of the two detectable proteins "said detectable protein" is referring to.

### ***Claim Rejections - 35 USC § 103***

The rejection of claims 17-19, 21-25 and 27-30 under 35 U.S.C. 103(a) as being unpatentable over Fell et al. in view of Casey et al. is withdrawn in view of applicant's amendments to the claims which add the limitation that the fusion polynucleotide comprises a nucleic acid encoding an immunoglobulin component and a nucleic acid encoding **at least two** detectable proteins. It is noted that applicant's arguments in regards to the teachings of Fell and

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Casey are found persuasive **only** in that neither Fell nor Casey teach or suggest that the chimeric immunoglobulin comprise two detectable proteins.

The rejection of claims 1-9, 11-14, and 52 under 35 U.S.C. 103(a) as being unpatentable over Fell et al. in view of Casey et al. and Rajewsky et al. is withdrawn in view of applicant's amendments to the claims which add the limitation that the fusion polynucleotide comprises a nucleic acid encoding an immunoglobulin component and a nucleic acid encoding **at least two** detectable proteins. It is noted that applicant's arguments in regards to the teachings of Fell, Casey, and Rajewsky are found persuasive **only** in that none of Fell, Casey, or Rajewsky teach or suggest that the chimeric immunoglobulin comprise two detectable proteins.

***Allowable Subject Matter***

Claims 1-2, 4, 7-10, and 52 are considered free of the prior art of record and allowable at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Dave Nguyen, can be reached at (571) 272-0731. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197.

Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Anne M. Wehbé', with a long horizontal line extending to the right.